

# Notice of Allowability

Application No.

10/718,846

Applicant(s)

KADDURAH-DAOUK ET AL.

Examiner

Mark L. Shibuya, Ph.D.

Art Unit

1639

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the telephonic interview of 8/7/2007.
2. ☒ The allowed claim(s) is/are 1, 2, 7, 8 and 13-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 8/7/2007.

7. ☐ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_

MARK L. SHIBUYA  
PRIMARY EXAMINER

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance: Atty Soroos argued that the provisional obviousness type double patenting rejection over 10/718765 is improper because the instant application was not filed before Serial No. 10/718765. This argument is found persuasive because both application have the same effective filing date, (see MPEP 804 (B, 1)).

Atty Hanley argued that the provisional obviousness type double patenting rejection over 10/718765 is improper because the restriction requirement in the instant application between methods of treatment of amyotrophic lateral sclerosis, (as in the instant application) and Huntington's Disease (as in Serial No. 10/718765). This argument is not found persuasive, because the only relationship between the instant application and Serial No. 10/718765, is through their parent application, Serial No. 08/853,174, now U.S. 6,706,764, (see MPEP 804.01 (A)). It is noted that U.S. 6,706,764 claims methods of treatment of both amyotrophic lateral sclerosis and Huntington's Disease, (see MPEP 804.01 (C)). Furthermore, the non-final Office action, mailed 8/19/2002, in Serial No. 08/853,174, states that search was extended to amyotrophic lateral sclerosis and Huntington's Disease, (see MPEP 804.01 (E)).

Finally, this argument is rendered moot because of the withdrawal of the provisional rejection is view of the above arguments of Atty Soroos.

The Declaration of Belinda Tsao Nivaggioli, Ph.D. under 37 CFR 1.132, filed 6/22/2007, is sufficient to overcome the rejection of claim of claims 1, 2, 7, 8 and 13-16

Art Unit: 1639

under 35 U.S.C. 103 (a) as unpatentable over Jennings (WO 94/17794), in view of Coffin, U.S. 5,492,930, based upon unexpected results of clinical trials of administration of creatine to patients with amyotrophic lateral sclerosis. These clinical trials show a significant increase in actual and extrapolated survival times in contrast to treatment with the approved drug Riluzole.

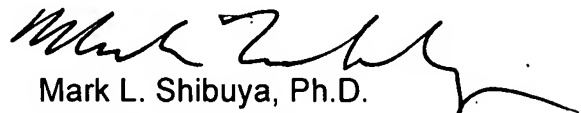
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya, whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Shibuya, Ph.D.  
Primary Examiner  
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